IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

REPLY BRIEF FOR THE APPELLANTS

Ex parte MAJEED et al

POTASSIUM HYDROXYCITRATE FOR THE SUPPRESSION OF APPETITE AND INDUCTION OF WEIGHT LOSS

Serial Number:	09/083,122
Filed:	May 22, 1998
Appeal Number:	Unknown
Group Art Unit:	1623
Examiner:	Oh, T.

A check in the amount of One Hundred and Fifty-five Dollars ($155.00, for a small entity) is enclosed to cover the official fee for this Reply Brief. In the event that any additional fees are required with respect to this paper, please charge Counsel's Deposit Account No. 01-2300.

Respectfully submitted,

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Date: May 17, 2001

(1) Real Party in Interest

The real party in interest is Sabinsa Corporation.

(2) Related Appeals and Interferences

There are no related appeals or interferences known to appellants.

(3) Status of Claims

Claims allowed: None.

Claims objected to: None.

Claims rejected: 1, 2 and 5-17.

(4) Status of Amendments

An amendment was filed after final rejection on May 11, 2000 to cancel claims 7-15 in order to reduce the number of issues for appeal. As of May 24, 2000, Examiner Oh indicated that the amendment filed on May 11, 2000 had not been received. In the Examiner's Answer, the Examiner confirmed that said amendments had been received and entered (see Examiner's Answer at page 2, section 4). Accordingly, these Claims, and the issues pertaining thereto, will not be discussed in this Reply Brief

(5) Summary of Invention

The invention is directed to a process of producing potassium hydroxy citric acid not in the form of a lactone and the potassium hydroxy citric acid made by said process. The process comprises extracting Garcinia fruit with an alcohol, treating the alcohol

extract with KOH to obtain a treated extract, refluxing the treated extract to obtain potassium hydroxy citrate precipitate, isolating the precipitate, washing the precipitate with alcohol, and drying the precipitate to obtain potassium hydroxy citric acid.

(6) Issues

Whether claims 1, 2 and 5-17 are unpatentable under 35 U.S.C. 103 over Lewis (*Methods in Enzymology*, vol. XIII, pp. 615-616, 1969) in view of Lowenstein (US 3,764,692).

(7) Grouping of Claims

Applicant argued in the Appeal Brief that Claims 1, 2 and 5-17 should be separated into the following two groups.

Group I. Claims 1, 2, 5, 6, 16 and 17, drawn to a process of producing potassium hydroxycitric acid not in the form of a lactone.

Group II. Claims 7-15, drawn to a compound made by the process of Group I.

It was the Applicant's position that the claims of Groups I and II did not stand or fall together because the claims of Groups I and II are patentably distinct. In the Examiner's Answer, the Examiner has stated that these claims are to stand and fall together for Applicant's failure to include both the statement that they do not and the reasons supporting such a statement. Applicant herein notes that the amendment to Claims 7-15 canceling Claims 7-15 has been entered. Accordingly, Applicant

respectfully submits that this point is now moot and concedes that the claims of Group I, i.e., all remaining Claims 1, 2, 5, 6, 16 and 17, stand and fall together.

Applicants also note that the Examiner has taken issue with the Claims as listed in the Appendix. However, as Examiner has been informed, Applicant has yet to receive a copy of the Examiner's allegedly correct claims. Accordingly, Applicants are unable to respond to Examiner's allegation at this time and reattach the previously submitted copies of Claims 1, 2, 5, 6, 16 and 17.

(8) Argument

Applicant previously argued that the claimed process differs from the process of Lewis at least in the following ways.

(i) The claimed process starts with the whole Garcinia fruit, while the process of Lewis starts with the rind of Garcinia fruit.

The Examiner responded that "if the skillful artisan in the art had desired to employ the whole Garcinia fruit for an economic reason as an alternative to its fruit rind, it would have been obvious to have used Lowenstein's whole fruit as the starting point in the Lewis process to produce the hydroxycitric acid." The Examiner cited to Lowenstein at Col. 1, lines 29-30 in which the acid is claimed to be isolated from "the fruit of Garcinia." It is by comparing this language to the language of the Lewis reference that the Examiner determined that there was "little difference as to the source of hydroxycitric acid."

Applicants respectfully disagree with this interpretation of the Lowenstein reference. While Applicants concede that Lowenstein does contain this quote, Applicants do not believe that the interpretation given to the reference by the Examiner is accurate. The reference teaches to the isolation of the acid by use of "the fruit of Garcinia." However, it then refers to the Lewis reference wherein the isolation methods referred to utilize the rind of the fruit. Applicants respectfully submit that this combination actually teaches to the use of the rind only.

If one desires to use the rind of the fruit (which is part of the fruit, and hence "the fruit"), one must use the fruit in order to obtain it. By referring to "known procedures" and the Lewis reference, in particular, the Lowenstein reference reinforces this reading as the only method for producing the acid prior to the present application was through using the rind alone. Accordingly, by placing these references together, Applicants submit that one of skill in the art would have read the Lowenstein reference as referring to the use of the rind of the fruit alone in its recitation in Col 1, lines 29-30. Accordingly, Applicant submits that the Examiner's analysis of this point is in error.

(ii) The claimed process extracts the whole Garcinia fruit with alcohol. In contrast, the process of Lewis follows a laborious procedure of extracting the Garcinia fruit rind with water, filtering the water extract to obtain a filtrate, concentrating the filtrate, and treating the filtrate with ethanol to remove a contaminant, i.e. the pectinous material, to be discarded as a precipitate leaving behind the acidic aqueous filtrate.

The Examiner claimed that this point was not convincing and stated that the only difference between the present application and the Lewis reference was that the Lewis process cooks the Garcinia rind in water and then conducts the aqueous extraction with alcohol while the present application claims Garcinia fruit containing water that is extracted with alcohol at a reflux temperature. The Examiner has taken the position that the present application claims "nothing more than the optimization of Lewis' process." The Examiner further stated that "it would have been obvious to have modified Lewis' process to the direct extraction with alcohol without cooking the Garcinia fruit rind so as to isolate the organic compounds containing hydroxy citric acid."

Applicants note, however, that the Examiner has not provided support for this sweeping statement. As stated in MPEP Section 2143.01, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Applicant can locate no reference in the Lewis reference that discloses what the Examiner has termed an "optimization" or its desirability. Therefore, Applicant respectfully submits that this analysis is also flawed and requests that this ground of rejection be reversed.

(iii) The claimed process treats the alcohol extract with KOH (see step e)), but the process of Lewis treats the aqueous filtrate with KOH (see step (7) in the table above).

The Examiner responded to this point by alleging that it was without merit. The Examiner stated that the purpose of adding alcohol to the Garcinia fruit is to extract

hydroxycitric acid. The Examiner has taken the position that Lewis expressly shows the addition of alcohol to the filtrate after cooking the rind in water on page 615, lines 20-25. The Examiner has alleged that it would have been obvious to one with ordinary skill in the art to have modified the Lewis process to match the process claimed in the present application.

Applicants respectfully submit that the Examiner has misunderstood the argument presented in the Appeal Brief. In the Appeal Brief, the Applicants argued that treating the alcohol extract with KOH in the claimed process was patentably distinct from the Lewis process of treating the aqueous filtrate with KOH. Applicants noted in their Brief that the alcohol extract in the claimed process contained substances in the Garcinia fruit which are alcohol soluble while the Lewis process contains water soluble substances. It was also noted that water soluble substances may not be soluble in alcohol. An example of such, potassium hydroxycitric acid, was given. Applicants contend that this is a significant difference between the two processes. While Applicants concede that the Examiner is correct in the citation to page 615, Applicants note that the process is a water based one, into which alcohol is later added as opposed to the alcohol based process of the present application. Applicants can find no discussion or motivation to modify the Lewis reference in such a manner as to produce the claimed process.

The Examiner further noted that the argument that water, acetone and alcohol do not serve the same purpose in the extraction of hydroxy citric acid was not convincing. The Examiner stated that it was merely pointed out that "solvents such as water, acetone and alcohol can be employed in the extraction process of Garcinia fruit

as disclosed in the references." However, the Examiner also conceded that the solvents have different partition coefficients such that the substances extracted with these solvents are not the same. In light of the preceding arguments, Applicant requests that this ground of rejection be reversed as well.

(iv) In the claimed process, after adding KOH, reflux is performed to obtain a precipitate of potassium hydroxy citric acid (see step f)), but in the Lewis process, after the addition of KOH, there is no refluxing (see step (7)) and step (7) obtains the heavy oily liquid which has to be washed with ethanol in step (9).

The Examiner responded to this by noting that the claimed process is involved in the extraction of the whole fruit containing water with alcohol and subsequently treating the extract with KOH. The Examiner stated that this process is similar to that disclosed in the Lewis reference in which it is described that "the dark brown filtrate containing water is concentrated and treated with ethanol, and further treated with KOH." The Examiner additionally stated that extraction requires the phase separation into the layers, but that the claimed alcohol extraction has no phase separation similar to the treatment of the filtrate with alcohol during the Lewis process. The Examiner explained that this is because alcohol can be miscible with water. The Examiner concluded that there were no patentably distinct steps involved in the claimed process and that the Applicants had failed to demonstrate unexpected results because no side-by-side comparison data illustrating the differences between the treatment of the Garcinia fruit

with alcohol and the treatment of the filtrate with alcohol as for the production of hydroxy citric acid had been presented.

The Examiner also argued that the statements made by made by the Applicants regarding the amount of heat generated by the addition of 40% KOH being less than the application of heat during refluxing was also not persuasive. The Examiner noted that the Lewis process teaches that "the acidic filtrate is neutralized by the cautious addition of 40% KOH, with careful stirring." This, as alleged, results in the formation of the desired product. Based upon this result, the Examiner alleged that the addition of 40% KOH to the aqueous filtrate generates sufficient heat to be the equivalent of refluxing the reaction to its conclusion. The Examiner also noted that the Applicants did not specify how much heat was applied during refluxing in the claim. The Examiner, with this statement as the basis, labeled the Applicant's evaluation concerning the level of heat in the reaction as "very subjective."

Applicants respectfully disagree with the Examiner's conclusions. Applicants again note that the present application's process requires the refluxing of the alcohol extract treated with KOH to obtain a precipitate of potassium hydroxycitric acid and that the Lewis process contains no such requirement. Applicants contend that there is no motivation to modify the Lewis process in a manner to duplicate the claimed process. Further, Applicants also note that the Examiner has not responded to Applicants' argument that the steps may not be reversed.

Additionally, Applicants contend that the meaning of reflux is well known to those in the art and that the allegation that a temperature needs to be provided is unfounded. The burden is on the Examiner to prove that the element of the reflux is contained

within the Lewis process. Applicants submit that this has not been done as no evidence has been presented which proves that an exothermic reaction is the equivalent of the refluxing temperature. Further, the Examiner has not even provided a personal affidavit to this effect.

Refluxing is defined as a "[t]erm used in distillation with a fractionating column for the liquid condensed from the rising vapor and allowed to flow down the column toward the still" (see The Condensed Chemical Dictionary, Seventh Edition, by Arthur and Elizabeth Rose, at page 812.) As seen by the definition, the refluxing temperature is essentially a boiling point. Absent the comments made by the Examiner that a mild exothermic reaction is produced in the Lewis process, there is no indication, express or otherwise, in the reference that either solvent is lost or that a boiling point is reached. Accordingly, Applicants submit that the refluxing element is not present in the Lewis reference.

(v) Steps a)-h) of the claimed process obtain a precipitate of potassium hydroxy citric acid of high purity requiring only one wash with alcohol. In contrast, steps (1)-(10) of the process of Lewis obtain a heavy oily liquid of potassium hydroxy citric acid of apparently low purity because Lewis requires washing the oily liquid 8 times to purify the potassium hydroxy citric acid as a yellow semisolid.

The Examiner stated that this was not persuasive. The Examiner noted that the Applicants did not specify any number of washings in the process and did not specify the purity of the desired product to be obtained from the claimed process. The

Examiner further stated that the Applicants did not show any unexpected results obtained from the claimed process as compared to the Lewis process.

Applicants respectfully disagree with the Examiner's conclusion and request that this basis of rejection be reversed. As Applicants alleged, the process disclosed in the present application is considerably simpler than that of the Lewis reference. While the Examiner is correct that no side by side study has been made, Applicants again note that there was no suggestion in the Lewis reference to abbreviate this step. Without this suggestion to modify the reference, the Examiner has not presented a valid obviousness rejection. Accordingly, Applicant requests that this rejection basis be reversed as well.

(vi) The claimed process is relatively simple, while the process of Lewis is rather laborious. The claimed process involves extracting Garcinia fruit with alcohol twice, treating the alcohol extract with KOH and refluxing to obtain potassium hydroxy citric acid (see steps b)-g) in the table above). However, the process of Lewis requires laborious procedures involving extracting Garcinia fruit rind with water, filtering and concentrating the water extract, adding ethanol to precipitate the pectinous material, removing the pectinous material precipitate by filtration, treating the filtrate with KOH, removing the supernatant to obtain the heavy oily liquid, washing the heavy oily liquid with ethanol 8 times, and discarding the ethanol to obtain potassium hydroxy citric acid as the yellow semisolid (see steps (2)-(10) in the table above).

The Examiner tried to refute this argument in the Examiner's Answer by stating that it is well-known in the prior art that solvents such as water and alcohol can be used in the extraction of Garcinia fruit. The Examiner stated that hydroxy citric acid derived from Garcinia fruit can be soluble in both alcohol and water. Based upon this assertion, the Examiner took the position that one with ordinary skill in the art would have had an expectation of success because of the solubility of hydroxy citric acid in alcohol to modify the Lewis process to extract the Garcinia fruit without undergoing the laborious cooking process. However, Examiner presents no evidence that such knowledge was present in the art at the time of the present application's filing.

Applicants disagree with the Examiner's rejection and relies upon its previous response.

Due to differences (i)-(vi) discussed above between the claimed process and Lewis and due to the lack of teachings in Lowenstein to remedy these differences of Lewis, Applicant renews its claim that Claims 1, 2, 5, 6, 16 and 17 should not have been deemed obvious over Lewis in view of Lowenstein.

(9) Appendix

Claims:

1. A process for the production of potassium hydroxy citric acid, which potassium hydroxy citric acid is not in the form of a lactone, comprising the steps of:

a) providing Garcinia fruit;

b) extracting the Garcinia fruit with an alkyl alcohol to obtain an extract;

c) repeating step b) to obtain another extract;

d) combining the extracts of steps b) and c) to obtain a combined extract;

e) treating the combined extract with potassium hydroxide to obtain a treated extract;

f) refluxing the treated extract to obtain potassium hydroxy citrate precipitate;

g) isolating the precipitate;

h) washing the precipitate with an alkyl alcohol to obtain a washed precipitate; and thereafter

i) drying the washed precipitate to obtain dried potassium hydroxy citric acid.

2. The process of claim 1 comprising:

a) providing Garcinia fruit;

b) extracting the Garcinia fruit with methanol at reflux temperature and collecting the extract;

c) repeating step b) an additional two times;

d) combining the three extracts of steps b) and c);

e) treating the combined extracts with methanolic potassium hydroxy at about pH 10 and reflux for about three hours to precipitate potassium hydroxy citrate;

f) filter the precipitate;

g) wash with methanol and dry under vacuum; and

h) mill, sift, blend, and pack the dried product under nitrogen.

5. A new technological process for commercial manufacturing of potassium hydroxy citric acid from natural source, which potassium hydroxy citric acid is not in the form of a lactone, said process comprising the steps of:

a) providing Garcinia fruit;

b) extracting the Garcinia fruit with an alkyl alcohol to obtain an extract;

c) repeating step b) an additional two times to obtain another extract;

d) combining the extracts of steps b) and c) to obtain a combined extract;

e) treating the combined extract with potassium hydroxide to obtain a treated extract;

f) refluxing the treated extract to obtain potassium hydroxy citrate precipitate;

g) isolating the precipitate;

h) washing the precipitate with an alkyl alcohol to obtain a washed precipitate; and thereafter

i) drying the washed precipitate to obtain dried potassium hydroxy citric acid.

6. The new technological process according to claim 5, further comprising milling, sifting, blending and packing the dried potassium hydroxy citric acid under nitrogen.

16. The process of claim 5, wherein the Garcinia fruit is Garcinia cambogia or Garcinia indica fruit.

17. The process of claim 16, wherein the Garcinia fruit is Garcinia cambogia.